DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 21, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:11am

PRESIDING: Ryan Logan, Vice Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Sheila K. W. Elliott
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner (departed at 11:10am)

MEMBERS ABSENT:
Rebecca Thornbury
Michael I. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David E. Brown, Director, DHP (arrived approx. 10:30am)
Elaine J. Yeatts, Senior Policy Analyst, DHP (arrived approx. 10:30am)
James Rutkowski, Assistant Attorney General

QUORUM: With eight members present, a quorum was established.

APPROVAL OF AGENDA: The agenda was approved as presented.

APPROVAL OF MINUTES: The following minutes were considered for approval:

- December 12, 2016, Public Hearing of Scheduling Certain Chemicals
- December 12, 2016, Full Board Meeting
- December 12, 2016, Formal Hearing
- January 17, 2017, Special Conference Committee
- February 1, 2017, Formal hearings
- February 21, 2017, Special Conference Committee
- February 28, 2017, Regulation Committee
- March 8, 2017, Special Conference Committee

The February 1st formal hearing minutes were amended to clarify that Mr.

Boone arrived at 1:55pm, because he was recused from the hearing regarding AcariaHealth Pharmacy, Inc. hearing. No other changes were made to the minutes presented.

MOTION: **The Board voted unanimously to adopt the minutes from December 12, 2016 through March 8, 2017 as presented and amended. (motion by Allen, second by Warriner)**

PUBLIC COMMENTS: Ms. Becky Laniers-Bower offered comment regarding the proposed amendments to 18VAC110-20-690 (F) for a controlled substance registration (CSR) to be issued to a facility participating in telemedicine when there is no DEA registrant on-site and the facility does not maintain a DEA registration. Ms. Laniers-Bower stated that most community service boards have an executive director that is often not a medical professional, but should perhaps qualify as the responsible party if the intent of the responsible party is to assume responsibility for all facility operations. Ms. Juran responded that the responsible party on the CSR is responsible only for ensuring compliance with the subject for which the CSR is issued, i.e, telemedicine in this case.

PRESENTATION OF 2016 PHARMACIST AND PHARMACY TECHNICIAN WORKFORCE REPORT

Elizabeth Carter, PhD with the Department of Health Professions presented the 2017 Healthcare Workforce Survey results to the Board. Dr. Carter indicated that their department is adding more professions to their surveys each year and by the end of the current year should have 30 professions that they survey. Dr. Carter provided the Board with an overview of the growing programs that the Healthcare Workforce Data Center oversees or partners with such as Virginia CareForce Snapshots, Virginia Health Workforce Briefs and the new Healthcare Occupational Roadmap which will be used in high schools to encourage students to join health professions that do not necessarily require a bachelor's degree such as pharmacy technician, respiratory therapist, and dental hygienist.

Mr. Saenz noted that the survey indicates 74% of our registered pharmacy technicians already hold national certification; 66% PTCB and 9% ExCPT.

REGULATORY ACTIONS:

- Adoption of Regulations to Schedule certain chemicals in Schedule I

There was a public hearing conducted at 9:08am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act.

MOTION: **The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:**
Classified as research chemicals:

- **6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD)**

- **6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD)**

Classified as powerful synthetic opioids:

- **N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl)**
- **N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl)**
- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl)**

Classified as cannabimimetic agents:

- **1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006)**
- **Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22)**

Classified as benzodiazepine:

- **Flubromazepam**

(motion by Warriner, second by Boone)

- Adoption of final regulations for Outsourcing Facilities

Ms. Juran provided a brief review of the emergency regulations for outsourcing facilities that are in effect December 7, 2015 through June 6, 2017 and stated there have been no comments on the proposed regulations.

MOTION:

The Board voted unanimously to adopt the final regulations for outsourcing facilities as presented which will replace the emergency regulations currently in effect (motion by Warriner, second by Cathcart)

- Adoption of final regulations for permitting facilities in which practitioners of the healing arts sell controlled substances

Ms. Juran provided a brief overview of the emergency regulations for permitting facilities in which practitioners of the healing arts sell controlled substances that are in effect December 7, 2015 through June 6, 2017 and noted there were no comments on the notice of intended regulatory action.

MOTION:

The Board voted unanimously to adopt the final regulations identical to the emergency regulations currently in effect for permitting facilities in which practitioners of the healing arts dispense controlled substances as presented (motion by Allen, second by Saenz)

- Adoption for final regulations for a prohibition on incentives to transfer prescriptions

Ms. Juran provided a brief background of the proposed regulation and the one comment received in opposition. The action results from a petition for rulemaking received in 2014 from a practicing pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews. The proposed language mirrors language adopted by Oregon several

years ago. The Board discussed the need for such prohibition on transfers as a public safety issue so that a more cohesive accurate medication record for a patient may be maintained. Ms. Juran stated there is a similar regulation that recently went into effect in Tennessee.

MOTION: **The Board voted unanimously to adopt the final regulations for prohibition on incentives to transfer prescriptions as proposed and presented. (motion by Warriner, second by Shinaberry)**

- Adoption of regulations for controlled substance registration and protocols for naloxone dispensing

The Board reviewed SB848 and HB1642 which authorizes trainers of the REVIVE! Training program who are authorized by DBHDS to possess and dispense naloxone free of charge at the conclusion of training events if a controlled substance registration is obtained by the entity for whom the trainer is dispensing. The board must amend its regulations for controlled substances registrations to facilitate this practice. Additionally, the second bill allows employees of certain agencies, e.g., Office of the Chief Medical Examiner and the Department of Forensic Science to possess naloxone as well for reversal of accidental overdose when exposed at work to potent chemicals. The recommendations from the Regulation Committee from February 28, 2017 were shared with the board. Ms. Cathcart suggested that all funeral home directors be alerted to this potential hazard as well.

ACTION ITEM: **Ms. Juran to share with the executive director of the Board of Funeral Directors and Embalmers Ms. Cathcart's suggestion that they educate their licensees on the importance of having naloxone on-hand for possible accidental overdose due to exposure of potent chemicals on the deceased bodies.**

MOTION: **The Board voted unanimously to amend 18VAC110-20-690, 18VAC110-20-710, 18VAC110-20-735, and Guidance Document 110-44 as presented and to adopt Guidance Document 110-45 as presented (motion by Warriner, second by Allen)**

- Adoption of emergency regulations for controlled substance registration for CSBs for purpose of telemedicine prescribing

The Board reviewed SB1009 and the proposed amendments to 18VAC110-20-690 (F) for a controlled substance registration (CSR) to be issued to a facility participating in telemedicine when there is no DEA registrant on-site with the patient and the facility where the patient is located does not maintain a DEA registration. It was stated that it may be cleaner to require a CSR specifically for this activity and to not allow an existing CSR to be amended for this activity. The CSR will allow the facility to apply for a corresponding DEA registration as a medical clinic. It was suggested that the CSR could have "telemedicine only" printed on the license to indicate that the CSR does not enable the ordering of drugs in Scheduled II-VI from a wholesale distributor, manufacturer, or pharmacy. A separate CSR could be issued for this purpose, if necessary.

MOTION: **The Board voted unanimously to adopt the emergency regulations for controlled substances registrations for the purpose of telemedicine as presented. (motion by Shinaberry, second by Allen)**

- Adoption of amendments to Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy*, chapter 20 (pharmacies and medical equipment suppliers)

The Board is currently undergoing a periodic review of regulations in chapters 20 and 50. In February 2017, the Regulation Committee reviewed suggested amendments to Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers). One suggested edit was offered to the amendments recommended by the Regulation Committee. It was noted that the phrase "A humane society or animal shelter,…" in 18VAC110-20-580 should be changed to "A public or private animal shelter,…." The Regulation Committee will consider suggested amendments to the third and final section of regulations at the May 2017 Regulation Committee meeting. The Board will adopt the proposed regulatory amendments for all of chapters 20 and 50 at its June 2017 full board meeting.

MOTION:

The Board voted unanimously to adopt the amendments to regulations in Parts IV, XIII through XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 (pharmacies and medical equipment suppliers) as recommended by the Regulation Committee and presented, to include an amendment to the language presented for 18VAC110-20-580 which strikes the term "humane society" in the first sentence and replaces with "public or private animal shelter". (motion by Warriner, second by S. Elliott)

DIRECTOR'S REPORT:

Dr. Brown spoke to the Board about the recent General Assembly session with regard to the opioid crisis in Virginia. In 2015, 811 Virginians died from an opioid overdose. Final numbers are not in for 2016, however, this number is expected to be over 1100 which is a rise of over 30% in 1 year. These overdoses are due mostly to heroin and illicit fentanyl. He stated 80% of opioid users began abusing drugs with a prescription opioid drug. Many of the bills in this General Assembly focused on addressing this topic. Prescribers must now check PMP for prescriptions given for opioids expected to last more than 7 days. E-prescribing for all opioid prescriptions expected by 2020. Board of Counseling is now beginning to regulate Peer Recovery Specialists which will allow reimbursement for some services in this area. The Department of Health will now begin a needle exchange program to reduce the incidence of hepatitis and HIV. It is believed that an abuser who interacts with representatives at a needle exchange program is more likely to seek help with addiction. Board of Medicine and Board of Dentistry are working to put emergency prescribing regulations in place for opioids and buprenorphine, the most diverted drug in southwest Virginia. There is also a bill that allows approved trainers of the REVIVE! Training program to dispense naloxone free of charge.

- Regulatory update

Ms. Yeatts briefly reviewed the chart of regulatory actions provided in the agenda and gave updates on the status of the regulatory actions in progress.

- Legislative update and overview of board of medicine emergency regulations governing prescribing of opioids and buprenorphine

Ms. Yeatts mirrored the sentiments provided in the director's report regarding the legislative update and gave an overview of the new Board of Medicine prescribing regulations for opioids and buprenorphine.

- Adoption of guidance document on hours of continuous work and breaks for pharmacists

Staff reviewed the suggested language for guidance for pharmacists taking breaks and hours of continuous work as recommended by the Regulation Committee.

MOTION: **The Board voted unanimously to adopt Guidance Document 110-39 as presented for Continuous Hours Worked By Pharmacists and Breaks (motion by Shinaberry, second by S. Elliott)**

- Revision of Guidance Document 110-20, practice by a pharmacy technician trainee

The Regulation Committee recommends revising this guidance document to redefine the start time for the allowable nine months of performing duties restricted to a pharmacy technician without holding registration as a pharmacy technician. The committee recommends the nine months begin when the pharmacy trainee starts actually performing the duties of a pharmacy technician trainee. In the past this was determined to be the date when the trainee first enrolled in a board-approved pharmacy technician training program. However, some programs are longer than nine months and the trainee does not begin performing duties restricted to pharmacy technicians until after nine months from enrollment.

MOTION: **The Board voted unanimously to amend Guidance Document 110-20, Practice by a Pharmacy Technician Trainee, as presented and recommended by the Regulation Committee. (motion by Saenz, second by Shinaberry)**

- Amend Regulation 18VAC110-20-310 to authorize partial filling of Schedule II prescription

Ms. Juran provided the Board with a brief overview of the CARA Act and the effect it had on the changes to partial filling of Schedule II prescriptions. The Regulation Committee reviewed the CARA Act at its meeting in February and requested that staff confer with Board counsel to determine if the language for the various allowances for partial filling of a Schedule II could be consolidated into one subsection. Ms. Juran stated counsel recommends keeping the various allowances in separate subsections which appears to mirror the federal allowances.

MOTION: **The Board voted unanimously to adopt a fast-track regulatory amendment of 18VAC110-20-310 by creating a new subsection E authorizing the partial filling of Schedule II prescriptions as indicated in the federal CARA Act. (motion by Allen, second by Boone)**

- Amend regulation 18VAC110-20-590, drugs in correctional

At the request of the pharmacist at the Department of Corrections and in consultation with DEA, the Regulation Committee recommends amendments to 18VAC110-20-590 to conform with federal rules that do

facilities	not allow Schedules II-V drugs that were dispensed to specific inmates to be returned to provider pharmacies for destruction. Currently, the regulations require all unused or discontinued drugs to be returned to a provider or secondary pharmacy. The amendment authorizes the destruction of such drugs at the correctional facility.
MOTION:	**The Board voted unanimously to adopt a fast-track regulatory amendment of 18VAC110-20-590 as recommended by the Regulation Committee to authorize the destruction of patient-specific drugs in Schedules II-V at the correctional facility in order to conform with federal rules. (motion by S. Elliott, second by Saenz)**
• Amend Guidance Document 110-9, pharmacy inspection deficiency monetary penalty guide	Staff provided an overview of the proposed changes to Guidance Document 110-9 as recommended by the Regulation Committee. Following discussion, it was determined that the suggested edit to Deficiency 21b should be changed to "Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better."
MOTION:	**The Board voted unanimously to amend Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide as presented and recommended by the Regulation Committee, with the exception of Deficiency 21b which was amended to read "Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better". (motion by Allen, second by Boone)**
• Adopt proposed amendments for NOIRAs resulting from petitions, refilling prescription in quantity up to total amount authorized and use of automated dispensing systems as emergency drug kits and stat drug boxes.	The Board reviewed two petitions for rulemaking provided in the agenda packet requesting clarifications regarding the use of automated dispensing devices as emergency kits and stat drug boxes and an allowance for a pharmacist to dispense a quantity of certain Schedule VI drugs up to the maximum allowable quantity prescribed, upon request by the patient. In February 2017, the Regulation Committee reviewed and proposed regulations to address the petitions. Ms. Shinaberry provided an additional amendment to subsection B in 18VAC110-20-320 to read "Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519, a pharmacist, using professional judgement and upon request by the patient, may refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration." This language intends to clarify the classes of drugs which a pharmacist is not allowed to refill up to the maximum quantity authorized on the prescription.
MOTION:	**The Board voted unanimously to adopt the following amendments: 18VAC110-20-320**

- **Subsection B - following "Schedule VI", change "shall" to "may" and strike "only" and "expressly";**
- **Subsection B – add "Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519, a pharmacist, using professional judgement and upon request by the patient, may refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration."**

18VAC110-20-540

- **In subsection 2, following "kit" insert "or an automated drug dispensing system, as provided in subsection B of this section,"**
- **Insert new subsection B to read "Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555."**

18VAC110-20-550

- **Insert "A" for subsection A**
- **Insert new subsection B that reads ""Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home".**

18VAC110-20-555

- **In (2) after "system", insert "unless the system is exclusively stocked with drugs that would be kept in a stat-box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration"**
- **Insert new #3 that states "For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading"**
- **Amend (3) by changing it to #4 and inserting in subsection 4a the phrase "including a drug that is stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550" following the phrase "A drug".**

(motion by Saenz, second by Shinaberry)

- Consider discontinuing the administration of the Virginia Pharmacy Technician Examination

The Board discussed the Virginia Pharmacy Technician Examination and the possibility of its discontinuation as the current contract with the examination administrator expires August 31, 2017. Mr. Saenz pointed out that 74% of our registered pharmacy technicians hold some type of national certification according to the health practitioner workforce data

survey. Staff has also contacted the Department of Education to confirm the ability for high school students to partake in both national exams if the Virginia Pharmacy Technician Exam was to be discontinued and board staff was informed that national certification exams would meet their students' needs. Staff would inform key stakeholders of this decision.

MOTION: **The Board voted unanimously to cease administering the Virginia Pharmacy Technician Examination at the completion of the current contract with the examination administrator, August 31, 2017 (motion by Saenz, second by S. Elliott)**

REPORTS

- Report on Board of Health Professions

Mr. Logan gave a brief overview of the Board of Health Professions meeting held on February 23, 2017 in which they discussed several items such as the new Healthcare Workforce Data Survey and sanctioning reference points and disciplinary case overload.

- Report on PMP

Mr. Orr presented information on the legislation in 2017 regarding the PMP. As of January 1, 2017, reporting to PMP within 24 hours of dispensing or the next business day has gone into effect. This General Assembly session, HB 2164 went into effect immediately upon passage, which placed gabapentin as a drug of concern which is now reportable to the PMP. As of January 25, 2017 and effective July 1, 2017, there are new regulations regarding reporting to PMP. There is a new platform for reporting and new required data elements such as the NPI of the prescriber, whether the prescription is a partial fill, a gender code, a species code and the electronic prescription reference number if the Rx is an electronic prescription. Also of note is that Virginia may now access the PMP for Washington DC as they now participate in the PMP interoperability program. In 2017 there were over 1.7 million requests to the PMP and over 66,000 registered users. There is also some integration of the PMP with electronic health records through "NarxCare" technology which will make the step of checking PMP easier for prescribers and pharmacists by integrating the PMP query into the existing workflow. Under a grant awarded by Purdue Pharma, the goal is to improve the performance, access and usability of the PMP program data for 18,000 prescribers and 400 pharmacists in the Commonwealth by the end of 2017.

- Report on Licensure Program

Mr. Johnson reported the Board currently licenses 35,025 individuals and facilities. The Board issued 876 licenses and registrations for the period of December 1, 2016 through February 28, 2017. Inspectors conducted 420 facility inspections including 197 routine inspections of pharmacies:

50 (25%) resulted in no deficiency, 74 (38%) with deficiencies and 73 (37%) with deficiencies and a consent order. Mr. Johnson discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012 and reviewed the most frequently cited deficiencies for the reporting period.

- Report on Disciplinary Program

Ms. Reiniers-Day reported that Pharmacy has a total of 363 cases as of the March 9, 2017, 135 patient care cases and 228 non-patient care cases. A new report charting the number of cases based on priority level was also provided to the board. The report was developed to assist staff with monitoring case management.

- Executive Director's Report

Ms. Juran indicated she did not have a handout for her report as indicated on the agenda. She reported that the Virginia inspectors began using the NABP universal inspection form as of March 2017. Additionally, she indicated she recently emailed letters to Senators Kaine and Warner, at the request of NABP and upon approval of the board chairman, expressing concern for proposed legislation allowing for the use of "Canadian" drugs. She reported that Beth O'Halloran recently presented information on the Drug Control Act to a Chinese Delegation visiting Virginia. Ms. Juran will present at the upcoming VSHP meeting and to students at Appalachian College of Pharmacy in May. Ms. Reiniers-Day has resumed full time work, Ms. Anne Joseph will cease assisting the board in an acting capacity, Ms. Kennia Butler began working for the board as disciplinary administrative assistant in January, and that the board is currently recruiting for an executive assistant. The board's cash balance remains in good condition.

JESSICA LIN SAFFELL

- Registration No: 0230-021805

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a possible summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Allen, the Board voted 7-0 in favor of the motion that, according to the evidence presented, the continued practice by Jessica Lin Saffell, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Jessica Lin Saffell to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Saffell for the indefinite suspension of her pharmacy technician registration for not less than two years.

- **CONSIDERATION OF CONSENT ORDER**

Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Boone, the Board voted 7-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.
Reconvene	The Board voted unanimously that only public business matters lawfully exempt from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting
MOTION:	**Upon a motion by Ms. Allen and duly seconded by Mr. Saenz, the Board voted 7-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Carter Allen Moore, a pharmacy technician.**
ADJOURN:	With all business concluded, the meeting adjourned at 1:48pm.

_____	_____
Ryan Logan, Vice-Chairman	Caroline D. Juran, Executive Director
_____	_____
DATE	DATE